

### **REMARKS**

After entry of this amendment, claims 1, and 3-5 are currently pending and under active consideration in the instant application. Claim 2 has been cancelled. Claims 1 and 4 have been amended. The subject matter of the amended claim recitations is fully supported in the specification. In particular, support for the amended recitation of claim 1 is found throughout the specification, *inter alia*, at page 4, lines 17-24 and Example 7, page 27. Support for the amended recitation of claim 4 is found throughout the specification, *inter alia*, at page 21, lines 2-4. No new matter has been added.

### **Claim Objections**

Claim 4 is objected to as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 4 has been re-written in independent form according to the Examiner's suggestion. Thus, this objection has been overcome and must be withdrawn.

### **Rejections under 35 U.S.C. §112**

Claim 2 is rejected under 35 U.S.C. § 112, second paragraph as being indefinite.

Claim 2 has been cancelled; thus, this rejection has been overcome and must be withdrawn.

### **Rejections under 35 U.S.C. §102**

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Pieroni *et al.* J. Virol. 71:6373-6380, 1997 ("Pieroni *et al.*") or Reed *et al.* J. Virol. 69:4127-4136, 1995 ("Reed *et al.*") or Drake *et al.* J. Biol. Chem. 274:34511-34514, 1999 ("Drake *et al.*").

Applicant respectfully disagrees with these rejections under 35 U.S.C. § 102(b) and, for the reasons detailed below, submit that the subject matter of presently amended claim 1 is in no way anticipated by the cited references.

To constitute an anticipation, each and every element of the claim must be disclosed in that one reference. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 U.S.P.Q.2d 1081 (Fed. Cir. 1985).

“Anticipation under Section 102 can be found only if a reference shows exactly what is claimed...” *Structural Rubber Prod. Co. v. Park Rubber Co.*, U.S.P.Q.1264 (Fed. Cir. 1984). As detailed below, the cited reference neither describes nor enables the presently claimed subject matter.

### **The Present Claim**

Claim 1, as now amended, is specifically drawn to an isolated, inactive polypeptide consisting of a full length NS2/3 protease or a truncation thereof having as its N-terminal residue any one amino acid from amino acid 810 to amino acid 906.

### **The Cited References**

#### ***Pieroni et al. and Drake et al.***

According to the Examiner, Pieroni *et al.* and Drake *et al.* teach a full-length NS2/3 protein which is isolated by virtue of its acellular synthesis.

#### ***Reed et al.***

According to the Examiner, Reed *et al.* teach truncated NS2/3 proteins which are enriched with respect to cellular components by virtue of extraction and immunoprecipitation.

### **Novelty of Present Claim**

In complete contrast, as presently amended, claim 1 is directed to an isolated, inactive polypeptide consisting of a full length NS2/3 protease or a truncation thereof having as its N-terminal residue any one amino acid from amino acid 810 to amino acid 906.

Applicants respectfully submit that one of the needs addressed and met by the present invention was the ability to isolate an inactive NS2/3 protease that does not proceed to auto-catalysis and thus can be activated later and used for large scale screening efforts (*see, e.g.*, pages 4-5 of the specification).

Applicant submits that in light of the present amendment of claim 1 and the remarks above, the cited references cannot and do not anticipate the claimed isolated, inactive polypeptide. Accordingly, the rejection based on Section 102(b) must be withdrawn.

**Rejections under 35 U.S.C. §103**

Claim 2 is rejected under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over Pieroni *et al.* or Reed *et al.*

Claim 2 has been cancelled; thus, this rejection has been overcome and must be withdrawn.


**Allowable Subject Matter**

Applicants respectfully acknowledge the Examiner's finding that claims 3 and 5 are allowed.

**CONCLUSION**

In light of the above amendments and remarks, Applicants submit that all of the objections and rejections have been overcome and must be withdrawn. Further, Applicants submit that the application is now in form for issuance and an early allowance is earnestly requested. If any issues remain, the Examiner is invited to telephone the Attorney at the number below.

Respectfully submitted,



Date: March 24, 2005

Susan K. Pocchiari  
Registration No. 45,016  
Attorney for Applicants

BOEHRINGER INGELHEIM CORPORATION  
Patent Department  
900 Ridgebury Road  
P.O. Box 368  
Ridgefield, CT 06877  
Tel.: (203) 798-5648  
Fax: (203) 798-4408